## THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 17

#### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte OSAMA O. IBRAHIM and JOSEPH E. SPRADLIN

Application No. 07/976,241<sup>1</sup>

ON BRIEF

Before GRON, ELLIS, and ROBINSON, <u>Administrative Patent Judges</u>. ROBINSON, <u>Administrative Patent Judge</u>.

#### **DECISION ON APPEAL**

This is a decision on appeal from the examiner's final rejection of claims 1-6, 9-11, and 14-21, which are all of the claims pending in the case. Independent claims 1 and 11 are illustrative of the subject matter on appeal and are reproduced below:

1. A method of manufacturing D-tagatose from cheese whey, milk, or cheese whey and milk, comprising the following sequential steps:

subjecting the cheese whey, milk, or cheese whey and milk to ultrafiltration to make a lactose permeate;

Application for patent, filed November 13, 1992. According to appellants this application is a continuation-in-part of application 07/821,969, filed January 16, 1992, now abandoned.

hydrolyzing the lactose permeate to make a lactose hydrolysate comprised of D-galactose and glucose;

subjecting the lactose hydrolysate to fermentation conditions whereby the glucose is selectively fermented to ethanol;

separating the D-galactose from the ethanol, making a solution having a concentration of from about 10% to about 60% by weight D-galactose;

subjecting the solution of D-galactose to enzymatic isomerization with L-arabinose isomerase at an isomerization pH from about 5.5 to about 7.0 and a temperature from about 50EC to about 70EC; and

wherein the yield of D-tagatose is from about 20% to about 45% by weight based on D-galactose.

11. A method of producing D-tagatose comprising enzymatic isomerization of D-galactose with L-arabinose isomerase at an isomerization pH from about 5.5 to about 7.0 and a temperature from about 50EC to about 70EC, wherein the D-galactose is in a solution having a concentration of from about 10% to about 60% by weight D-galactose and the yield of D-tagatose is from about 20% to about 45% by weight based on D-galactose.

The references<sup>2</sup> relied upon by the examiner are:

Beadle et al. (Beadle) 5,002,612 Mar. 26, 1991

Barker et al. (Barker) 4,069,104 Jan. 17, 1978

Fiehring et al. Chemical Abstracts, Volume 73(25), p129742e (1970)

<sup>&</sup>lt;sup>2</sup>The examiner has relied upon two abstracts from <u>Chemical Abstracts</u> in support of the conclusion of obviousness. A patentability determination under 35 U.S.C. § 103 is fact specific. Almost by definition the full text document which is abstracted is more fact rich than the abstract. We strongly urge the examiner to premise his patentability determinations in the future, upon the most fact rich record which can reasonably be developed. It is the experience of the board that review of the full text document when a rejection is premised upon an abstract will most likely significantly strengthen or weaken the examiner's position. Rarely does consideration of the full text document leave one in the same position where one was after considering the abstract alone. Here, we have considered the abstracted German document and the translation thereof.

Hartley et al. (Hartley), <u>Chemical Abstracts</u>, Volume 114(25), p242021x (1990) A reference considered by this panel:

Fiehring et al.(Fiehring)<sup>3</sup> German Democratic Republic Patentschrift DD 72 459 April 12, 1970

### **GROUND OF REJECTION**

Claims 1-6, 9-11, and 14-21 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Beadle, Barker, Fiehring, and Hartley.

We affirm-in-part.

#### **BACKGROUND**

At page 3 of the specification, applicants describe the invention as relating to a method of producing D-tagatose by employing L-arabinose isomerase in the enzymatic isomerization of D-galactose recovered from the fermentation of a lactose hydrolysate.

The lactose hydrolysate is stated to be derived from cheese whey and/or milk. Applicants indicate that the D-tagatose is useful as a low calorie sweetener or bulking agent.

<sup>&</sup>lt;sup>3</sup>The examiner in his answer and appellants in their principal and reply briefs have referred to the abstract from <u>Chemical Abstracts</u> of Fiehring. We refer, in our opinion, to a translation of the abstracted German Patentschrift and the translation of this document prepared by the PTO Translation Branch, in August 1995, a copy of which is attached to this decision.

## **DISCUSSION**

## **Grouping of the Claims:**

At page 5 of the Appellants' principal brief (principal brief), appellants state that the claims do not stand or fall together and sets forth the following groupings:

Group One - Claims 1 - 6, 9, and 10.

Group Two - Claims 11 and 14 - 21.

Appellants have not separately argued the claims within each group. Therefore, we have separately considered the final rejection only as it applies to claim 1, as representative of claims 1-6, 9 and 10 of Group One, and claim 11, as representative of claims 11 and 14-21 of Group Two.

## The rejection under 35 U.S.C. § 103

Claims 1-6, 9-11, and 14-21 stand rejected under 35 U.S.C. § 103 as being obvious over Beadle in combination with Fiehring, Hartley and Barker.

## Claims 1-6, 9 and 10:

The examiner has relied upon Beadle as substantially teaching a method of manufacturing D-tagatose from lactose, whey or deproteinized whey as claimed (Answer, pages 4-5). The examiner acknowledges that Beadle does not disclose the use of the yeast and/or bacteria species described in appellants' fermentation step (Answer, page 5). In fact, Beadle does not disclose a fermentation step at all. In attempting to supply that

which is missing from the disclosure of Beadle, the examiner has relied on Fiehring as disclosing the use of yeasts, such as <u>Saccharomyces sp.</u>, to remove lactose and the cleavage products, galactose and glucose, from milk. (Answer, paragraph bridging pages 5-6). Hartley is said to teach that "yeasts such as <u>Saccharomyces cerevisiae</u> can be useful for the preparation of sugars from whey and the fermentation of ethanol from lactose. (Answer, page 6). Barker is said to teach "a process for the production of tagatose via the conversion of galactose in the presence of L-arabinose isomerase---." (Answer, page 6). The examiner then concludes (Answer, page 7):

It would have been obvious to modify the conventional method steps and reaction conditions taught by the Beadle et al patent to optimize the production of tagatose in view of the Fiehring et al (Abstract) which teaches the conventional use of yeasts, viz., <a href="Saccharomyces sp">Saccharomyces sp</a> to remove lactose and the cleavage products, galactose- and glucose-cultures, in a process for the preparation of milk free carbohydrates and in view of the Harley (Abstract) which teaches that the same species of yeasts can be used for the preparation of sugars from whey and the fermentation of ethanol from lactose. Also, it would have been obvious to modify the method steps and reaction conditions taught by the Beadle et al. reference to optimize production of the sugar tagatose in view of the Barker et al. reference which teaches that the use of metal ions and L-arabinose isomerase enzyme derived from microorganisms can be used in a process for production of the sugar tagatose.

The examiner bears the initial burden of presenting a <u>prima facie</u> case of obviousness. <u>In re Oetiker</u>, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444

(Fed. Cir. 1992). On the record before us, the examiner has failed to establish a <u>prima facie</u> case of unpatentability of the claimed subject matter. Fiehring and Hartley do not

supply that which is missing from Beadle. We agree with appellants' statements (principal brief, page 11-12):

There is no suggestion in Fiehring et al. of the use of selective fermentation to separate glucose from galactose as is required according to the Group One claims.

There is no suggestion in Hartley et al. that it would be possible to selectively ferment one sugar to separate it from another.

A reasonable reading of Fiehring indicates that lactose and its decomposition products galactose and glucose are <u>all</u> being removed from the milk products described. Similarly, Hartley does not disclose or suggest the selective fermentation of glucose over D-galactose. To establish a <u>prima facie</u> case of obviousness, there must be more than the demonstrated existence of all of the components of the claimed process. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge can not come from the applicants' invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). The extent to which such suggestion must be explicit in or may be fairly inferred from, the references, is decided on the facts of each case, in light of the prior art and its relationship to the invention. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed inventions using applicants' claimed invention as a template

and selecting elements from references to fill the gaps. In re Gorman, 933 F.2d 983, 986-987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). We find no reasonable suggestion, motivation, or direction which would have suggested to one of ordinary skill in this art to use the microorganisms of Fiehring or Hartley in the process of Beadle, in order to selectively convert glucose, in the presence of galactose and lactose, to alcohol. Barker, similarly, does not disclose a selective fermentation step required by claim 1.

We conclude that the examiner has failed to establish a <u>prima facie</u> case of unpatentability of the claimed subject matter. Where the examiner fails to establish a <u>prima facie</u> case, the rejection is improper and will be overturned. <u>In re Fine</u>, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). We therefore reverse the rejection of claims 1-6, 9 and 10 under 35 U.S.C. § 103.

## Claims 11 and 14-21:

As discussed above, the appellants have grouped claims 11 and 14-21 together as Group 2. Accordingly, we elect to consider the issues as they appl to representative claim 11. (37 CFR 1.192(c)(7)). Representative claim 11 differs from claim 1 in being directed solely to the enzymatic isomerization of D-galactose to D-tagatose in the presence of L-arabinose isomerase. While claim 11, and the other claims in Group Two, are rejected over the combination of Beadle, Barker, Fiehring and Hartley, the disclosures of Fiehring and Hartley do not relate to the isomerization of D-galactose to D-tagatose. The relevance of Beadle to these claims is also unclear. The correlation of the disclosed chemical isomerization process of Beadle to the enzymatic isomerization process claimed

is not established by the examiner. More relevant to the claimed subject matter is Barker which discloses an enzymatic isomerization of galatose to tagatose as well as the associated reactions conditions for this type of process. As pointed out by the examiner, Barker teaches (Answer, page 6) "[a] process for the production of tagatose via the conversion of galactose in the presence of L-arabinose isomerase." While Barley does not disclose the optimum reaction parameters and conditions for conversion of Dgalactose to D-tagatose, it does disclose the optimum isomerization conditions for converting glucose to fructose as well as indicating the broader preferred conditions for such processes. (Col. 6, lines 15-26). These conditions, including a pH range of 6-10, a temperature range of 50-100 C and a concentration of starting material of 30% to 50% w/w, reasonably appear to overlap the reaction conditions of claim 11. At the very least, Barker establishes that the reaction conditions relating to pH, temperature and concentration of starting materials are result effective variables. This is sufficient to establish a prima facie case of obviousness as it relates to the claimed method. This accords with the rule that discovery of optimum values of result effective variables in a known process is ordinarily within the skill of the art. In re Boesch, 617 F.2d 272, 276, 223 USPQ 785, 788 (CCPA 1980) and cases cited therein.

Thus, we find that the examiner has established a <u>prima facie</u> case of unpatentability as to the claimed method of enzymatically isomerizing D-galactose to D-tagatose in the presence of arabinose isomerase. Where, as here, a <u>prima facie</u> case of obviousness has been established, the burden of going forward shifts to the appellants. <u>In</u>

<u>re Piasecki</u>, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984), <u>In re Rinehart</u>, 531 F.2d 1048, 1052, 189 USPQ 143, 147, (CCPA 1976).

Appellants initially argue that the combination of the references, relied upon by the examiner are a result of hindsight reconstruction. (Principal Brief, page 7). However, as we have noted, there is no need to combine any of the other cited references with Barker, since Barker, standing alone, is sufficient to establish the prima facie case of unpatentability as to the enzymatic isomerization process of claim 11. Appellants also urge (principal brief, page 9) that Barker is deficient because: "No description of the conditions for such conversion are suggested." We do not agree. As discussed, supra, Barker teaches reaction conditions which are sufficient to practice the claimed process. To the extent that appellants urge that they have discovered "[t]hat L-arabinose isomerase can be used effectively under the conditions claimed to produce D-tagatose from Dgalactose, therefore, was unexpected and unobvious" (Principal Brief, paragraph bridging pages 9-10), we note that appellants have presented no evidence in support of the alleged unexpected results. It is well settled that a prima facie case of obviousness may be rebutted "where the results of optimizing a variable, which was known to be result effective, [are] unexpectedly good." In re Boesch, supra; In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8-9 (CCPA 1977). However, where the difference between the claimed invention and the prior art is some range or other variable within the claim, the appellants must show that the particular range is critical, generally by showing that the claimed range

achieves unexpected results relative to the prior art range. <u>In re Woodruff</u>, 919 F.2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990).

On the record before us, the examiner has established a <u>prima facie</u> case of unpatentability of the claimed subject matter which appellants have not overcome by arguments or evidence.

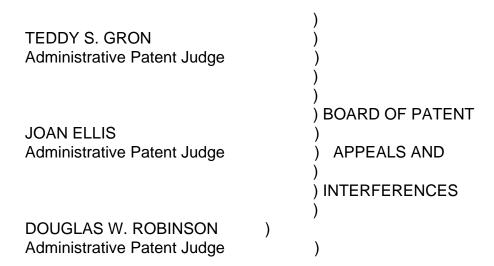
Therefore, the rejection of claims 11 and 14-21 under 35 U.S.C. § 103 is affirmed.

## SUMMARY:

The rejection of claims 1-6, 9 and 10 under 35 U.S.C. § 103 is reversed. The rejection under 35 U.S.C. § 103 of claims 11 and 14-21 is affirm.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

#### **AFFIRMED-IN-PART**



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